

REMARKS

Claims 1, 4-6, 13, 14, 17, 27 and 57-62 are pending in the application. Claims 27 and 57-62 have been withdrawn from further consideration as being drawn to a non-elected invention. Claims 1-6, 13, 14 and 17 have been examined on the merits.

Information Disclosure State (IDS)

In compliance with 37 CFR 1.98(a)(2), a legible fresh copy of each cited foreign patent document, non-patent literature publication, and cited reference in 1449 form submitted on February 26, 2006 will be filed for consideration in due course.

Specification

The specification has been objected to for including non-capitalized letters for a Trademarked word. The specification has been amended to incorporate capital letters for the Trademarked word. Therefore, it is believed that this objection has been overcome.

Rejection Under 35 U.S.C. §101: Non-statutory subject matter

Claims 1-6, 13, 14 and 17 have been rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested. Claims 1-6 have been amended to include the word "isolated". The claims no longer read on non-statutory subject matter. It is believed that this rejection has been overcome.

Rejection Under 35 U.S.C. §112: Second Paragraph

Claims 1-6, 13, 14 and 17 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested. The objected to claims have been amended to further define the claimed invention. Therefore, it is believed that this rejection has been overcome.

Rejection Under 35 U.S.C. §112: First Paragraph (Written Description)

Claims 5 and 6 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

The present application is based on the discovery that the MGFR portion of MUC1 receptor plays a significant role in the proliferation of cancer cells. Applicant has further demonstrated in the present application that bi-valent MGFR specific antibodies stimulated growth of cancer cells, whereas mono-valent antibodies inhibited growth of cancer cells. Dimerization of the MUC1 receptors such as by using MGFR specific bi-valent antibodies causes proliferation of these cancer cells, but mono-valent antibodies act to prevent such cancer cell proliferation by preventing dimerization of MUC1 receptors.

Applicant has disclosed a significant area on the MUC1 receptor protein for which mono-valent antibody is desired to be made. The present application exemplifies antibody production against a particular sequence, the PSMGFR as well as a variation of PSMGFR called var-PSMGF. Applicant has further provided a written description of this area, and also provided an antibody made against a variant PSMGFR in this region. Therefore, the present application provides written description sufficient to show possession of the antibodies against the claimed MGFR region. Applicant submits that the written description requirement

has been met for the claimed subject matter. Removal of this rejection is respectfully requested.

Rejection Under 35 USC § 102(e) Over Bamdad et al. '199 (US 2003/0036199)

Claims 1-6, 13, 14 and 17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Bamdad et al. '199. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

The present application claims the benefit of priority to PCT/US2005/032821 (See the Declaration), which in turn claims priority to U.S. Application No. 09/996,069, which is the application number for the cited Bamdad '199 patent application publication. Therefore, Bamdad '199 is not citable against the present application.

Rejection Under 35 USC § 102(e) Over Kufe et al. '685 (WO 02/22685)

Claims 1-6, 13, 14 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Kufe et al. '685. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Kufe discloses MUC1/ECD region, which roughly corresponds to PSMGFR sequence of the present invention. Kufe also discloses making an antibody to a fragment of the sequence. However, Kufe fails to understand the vast activity difference in effect between monovalent and bivalent MGFR specific antibody. Kufe fails to disclose the actual making of a monovalent antibody. Therefore, Kufe fails to provide an enabling disclosure of a monovalent antibody.

Rejection Under 35 USC § 102(e) Over Wreschner et al. '324 (US 2005/0019324)

Claims 1-6, 13, 14 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Wreschner et al. '324. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Wreschner discloses a mono-clonal antibody (BOS7D10) against MUC1 that inhibits cell growth. However, the disclosed antibody appears to be a bi-valent antibody. Since Wreschner is silent as to the anti-cell proliferation effects of the mono-valent antibody over bi-valent antibody, the presently claimed mono-valent antibody is distinguished over the bi-valent antibody described in Wreschner.

**Rejection Under 35 U.S.C. §103(a) Over Kufe et al. '685 (WO 02/22685) In View Of
Bamdad et al. '199 (US 2003/0036199)**

Claims 1 and 17 have been rejected under 35 U.S.C. §103(a) as being "obvious" over Kufe et al. '685 in view of Bamdad et al. '199. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Since Bamdad '199 is a priority application and therefore cannot be cited against the present application, this rejection is fails to be applicable to the present application.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. **502486** for any fees required under 37 CFR § 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. **502486**.

Serial No. 10/570,010

**Patent
13150-70089US**

Respectfully submitted,

JHK Law

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